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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,677	03/11/2002	Cecilia Leao	21133US0XPCT	1092

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 07/29/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,330

Applicant(s)

BONNIN ET AL.

Examiner

Irene Marx

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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The application should be reviewed for errors, and conformity with domestic practice. Error occurs, for example, in the designation "*nouxii*". It appears that the correct species name is "*rouxii*". Error occurs also in claim 13 in the use of "to number". The correct terminology is "to enumerate" or "to count". In addition error occurs in the spelling of "ballii" in claim 1.

The status of the parent case(s) should be updated.

Specification

The application is objected to because it is replete with alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required.

The amendment filed 3/11/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

No basis or support is found in the present specification for the material in Table 3 and 4 pertaining to 6 strains of *Zygosaccharomyes* "*nouxii*" tested

In addition, the amendment to the specification to replace the values indicated for some oligoelements raises the issue of new matter. Similarly, the replacement of "HCl" with "NaOH" as well as the replacement of "1M" with "10M" raises the issue of new matter. Similarly, the amendment to replace "annealed" with "mixed" and now with "brought" does not appear to have basis in the as-filed specification.

Also there is no basis or support for the substitution of the paragraph deleted at page 15 with the paragraph(s) on page 15a.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 are confusing in the recitation of "appropriated". It is unclear whether "appropriate" or "proprietary" is intended. Claim 7 fails to find proper antecedent basis in claim 1 for "4.3-4.8" as a range.

Claim 5 is vague and indefinite in the use of parenthesis to denote concentrations of ingredients. This does not constitute a positive recitation of the limitations intended.

Claim 8 is vague and indefinite in the recitation "in the usually used concentration for this purpose, for use with mixed population samples containing bacteria". To begin with, concentration of antibiotics would depend on the nature of the antibiotic used. In addition, the purpose and nature of the antibiotic is unclear in this context.

Claim 9 is confusing as written. The intent of "that is in its liquid form" is not clearly delineated". Is it the agar?

Claim 10 is vague and indefinite in the recitation of "the desired value(s)" with respect to concentration and pH. No concentrations or final pH are indicated in the claim 1 as "desired". Thus, the intended limitations are uncertain and ambiguous.

Claim 12 is confusing in that it is not clearly delineated whether "optionally" pertains to an antibiotic inhibitor only or to agar also.

Claim 13 fails to find proper antecedent basis in claim 12 for "inoculating" and "incubating".

Claim 14 is confusing in the recitation of "wines, as well as in other beverages or food containing or not mixed yeast populations". The intended meaning is unclear with respect to the material recited.

Claim 15 is confusing in the recitation of "yeast identification galleries". It is unclear what is intended by this terminology.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in

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Ex parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83

USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3-4 and 6-7 recite the broad recitation 0.05% to 0.2, respectively "acid-base indicator..." or "pH is.." and the claim also recites "preferably..." which is the narrower statement of the range/limitation. In addition, in claim 16 the phrase "particularly in the quality and process control industry..."

Claims 12 and 14-16 provide for the use of a medium, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12 and 14-16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-9 and 12-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a medium as recited in claim 10, does not reasonably provide enablement for a medium comprising undisclosed amounts of formic acid, for example. The specification does not enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

From the record of the present written disclosure, to be differential and selective a medium for *Z. bailii* or *Z. bisporus* requires between 0.1-0.5% v/v of formic acid (See, e.g., specification, page 7). In addition, Schuller *et al.* disclose that unless the formic acid concentration is between 0.3% and 0.5% (vol/vol) and the glucose concentration is about 0.1% wt/vol., false positive results are obtained (See, e.g., page 1571, col. 2). Therefore the concentration of formic acid is a critical element of the claimed invention and should be part of the invention as claimed.

A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement. See Gentry Gallery, 134 F.3d at 1480, 45 USPQ2d at 1503; In re Sus, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962) (“[O]ne skilled in this art would not be taught by the written description of the invention in the specification that any aryl or substituted aryl radical’ would be suitable for the purposes of the invention but rather that only certain aryl radicals and certain specifically substituted aryl radicals [i.e., aryl azides] would be suitable for such purposes.”) (emphasis in original). A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may also be subject to rejection under 35 U.S.C. 112, para. 1, as not enabling, or under 35 U.S.C. 112, para. 2. See In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976); In re Venezia, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); and In re Collier, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). See also MPEP § 2172.01. The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117.

In addition, the medium is touted as being selective for “*Z. bailii*” or “*Z. bisporus*”. Yet the taxonomic status of these microorganisms is not clearly defined. See, e.g., ATCC print out. Strains of at least *Z. rouxii* appear to be so similar to strains of *Z. bailii* or *Z. bisporus*, and are now reclassified as such and do not appear to be clearly

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distinguishable.

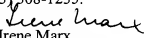
Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.


Irene Marx
Primary Examiner
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